

NELAP ON-SITE ASSESSMENT ASSESSOR TRAINING MANUAL

CHAPTER 1 INTRODUCTION

1.0 Purpose of this manual

This manual presents the required procedures for conducting a laboratory on-site assessment as required by the National Environmental Laboratory Accreditation Conference (NELAC) standards. The procedures and requirements presented in this document are based on relevant portions of the NELAC standards for laboratory accreditation.¹ They must be used by all on-site assessors representing environmental laboratory accrediting authorities that are recognized by the National Environmental Laboratory Accreditation Program (NELAP). Application of the procedures described in this manual is a requirement for NELAP recognition of assessment personnel.

This manual serves two principal purposes:

1. It is the course text for the NELAC On-Site Assessor training course.
2. It is an up-to-date reference manual for laboratory assessors.

As such, its primary benefit is to ensure a level of national consistency in NELAC on-site assessments, on a continuing basis.

The manual serves numerous other purposes as well. For example, it:

- Describes required records and documentation of the on-site assessment process so that all assessment findings are fully traceable and can be meaningfully reviewed and evaluated in the event of a dispute;
- Establishes procedures which enable the on-site assessment process to be as efficient as possible;
- Defines the duties and responsibilities of all on-site assessment personnel throughout the assessment process and within the framework of the NELAP accreditation process, and
- Provides a tool for laboratory personnel so that they can be well-prepared for assessments and participate fully in the assessment process.

It is a goal of NELAP to ensure that all on-site assessment personnel achieve a uniformly high standard of performance. This manual and the accompanying training course and related materials are the principal tools to be used in fulfilling that goal.

¹ This version of the manual reflects the draft NELAC standards as of July 3, 1997. Each year at their annual meeting, the members of NELAC consider modifications to the standards and, following the annual meeting, the standards are revised to reflect any changes adopted by the Conference. This manual will be updated, as necessary, to reflect any changes to the standards made by the Conference.

1.1 NELAC Overview

The National Environmental Laboratory Accreditation Conference (NELAC) is a voluntary association of state and Federal officials organized for purposes of developing national performance standards for environmental laboratories and to foster the generation of environmental laboratory data of known and documented quality. The national performance standards established by NELAC are adopted voluntarily by the State and Federal accrediting authorities that participate in NELAC. Through a system of standing and administrative committees which convene throughout the year, and two national meetings each year, NELAC provides a forum for discussing issues related to environmental laboratory performance in which all stakeholders in the laboratory accreditation process can participate.

NELAC is led by an eleven-member Board of Directors nine of whom are chosen from among the State and Federal government members of the Conference. NELAC is sponsored by the U.S. Environmental Protection Agency (EPA). EPA funds NELAC activities and staffs the National Environmental Laboratory Accreditation Program (NELAP), which provides staff support to the NELAC Board of Directors and performs functions outlined in the NELAC Constitution and the Program Policy and Structure Chapter of the NELAC standards (Sections 1.0 and 2.0, respectively). The NELAP Director and Executive Secretary, both EPA employees, serve on the NELAC Board of Directors.

The NELAC membership consists of Voting Members and Contributors. Voting members are officials employed by the government of the United States, the States, U.S. territories, or the District of Columbia who are actively engaged in environmental regulatory programs or accreditation of environmental laboratories. Contributors include representatives from the private sector (e.g., the private laboratory community or regulated industries), academia, trade associations, counties, municipalities, other subdivisions of the States, territories and possessions of the U.S., other Federal government representatives not engaged in environmental activities, and any others with an interest in NELAC.

The NELAC organization consists of three administrative committees:

- The Conference Management Committee
- The Nominating Committee
- The Membership and Outreach Committee

Each has a chair and members drawn from the Voting Members and Contributors of NELAC. There are also seven Standing Committees:

- The Program Policy and Structure Committee
- The Accrediting Authority Committee
- The Quality Systems Committee
- The Proficiency Testing Committee
- The On-Site Assessment Committee
- The Accreditation Process Committee

➤ The Implementation Committee

Each of these committees is also led by a chair, elected by the committee members, and consists of members selected from the NELAC Voting Members and Contributors. All of the committees report to the Board of Directors.

The Program Policy and Structure Committee is responsible for developing and maintaining the NELAC Constitution and By-Laws and the Policy and Structure Chapter of the NELAC standards. The Implementation Committee is responsible for developing and recommending approaches to facilitating implementation of the NELAC standards by the States², territories and U.S. possessions, through state legislation and regulations. The remaining five Standing Committees are each responsible for initially developing and routinely reviewing the other sections of the NELAC standards for laboratory accreditation. Specific to this training manual, the On-Site Assessment Committee is responsible for developing NELAC standards for conducting on-site assessments of laboratories. These standards address both performance criteria for laboratories and the on-site assessment process. The Committee is also responsible for producing this manual and ensuring that it is regularly updated to reflect any changes made in the NELAC standards.

As stated previously, the NELAC committees meet throughout the year to consider issues related to the development of the standards and to develop new or revised standards, as deemed appropriate. Once every year, the NELAC membership meets for its annual Conference at which new or amended standards are brought before the membership for adoption by the Voting Members. Although Contributors do not vote in committees or on the adoption of new standards, they participate in all committee activities and in floor discussions at the Conference. NELAC also holds an interim meeting each year, at which the committees present and discuss important issues and proposed changes to the standards.

To achieve national uniformity in the adoption and implementation of NELAC standards by accrediting authorities, the NELAC standards include requirements for accrediting authorities that must be met in order to be granted NELAP recognition. NELAP implements and enforces these standards through a process of application review, on-site assessment, and approval by accrediting authorities. This process has been designed to ensure that full reciprocity among NELAP accrediting authorities will be achieved. The NELAP Director will establish an Accrediting Authority Review Board to advise EPA on implementation of its accrediting authority oversight program.

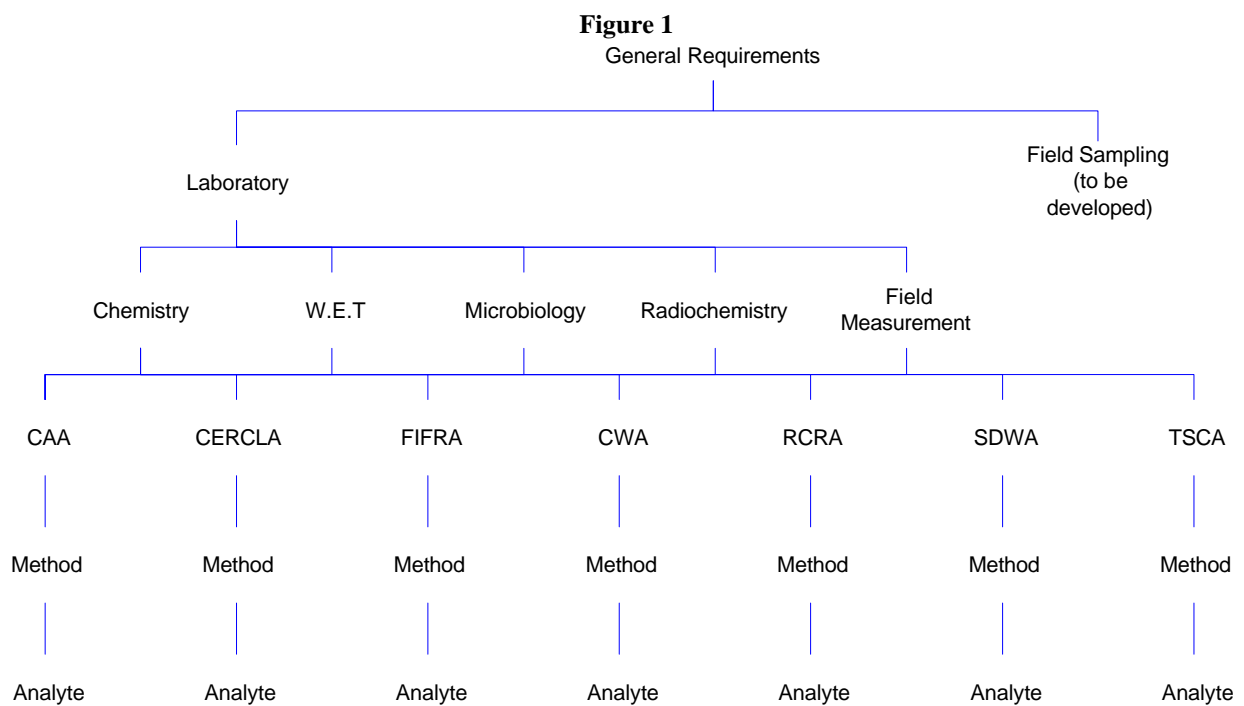
In order to maintain NELAP recognition, accrediting authorities must meet all of the NELAC standards for accrediting authorities. These include requirements that all on-site assessments of laboratories be conducted in accordance with the standards and with the procedures and criteria established in this manual. In addition, NELAP-recognized accrediting authorities must employ on-site assessment personnel who possess the

²Throughout this document, the terms States, State governments, and State accrediting authorities should be understood to include States, territories, U.S. possessions, and the District of Columbia.

qualifications established by the standards and have successfully completed the NELAP on-site assessment training program.

1.2 Fields of Testing

The NELAP Fields of testing are based a tiered approach consisting first of general laboratory and field sampling requirements in the first tier. The second tier consists of accreditation for chemistry, whole effluent toxicity, microbiology, radiochemistry and field measurements. The third tier includes the laboratory and method requirements for the various EPA regulatory programs which include the Clean Air Act, Comprehensive Environmental Response and Liability Act, Federal Insecticide, Fungicide and Rodenticide Act, Clean Water Act, Resource Conservation and Recovery Act, Safe Drinking Water Act, and the Toxic Substances Control Act. The tiered Fields of Testing are graphically displayed in Figure 1-1.



This figure and the supporting text will be reviewed at a later date to accommodate the unique characteristics of the GLP program, taking into consideration the recommendations of the Environmental Laboratory Advisory Board.

1.3 Roles and Responsibilities

Section 1.6 of the NELAC standards state that EPA's roles in NELAC are to:

- Oversee and evaluate accrediting authorities on a regular basis;
- Establish and maintain a national data base on the status of accrediting authorities and laboratories;
- Establish a program for evaluating, approving and reporting on environmental laboratory accreditation programs implemented by state accrediting authorities;
- Evaluate state and Federal principal laboratories in accordance with the NELAC standards;
- Ensure that a system is developed and implemented to evaluate and approve providers of laboratory proficiency tests;
- Establish and maintain an electronic bulletin board to distribute NELAC information to the public; and
- Provide staff support to NELAC.

EPA accomplishes these functions through the staff assigned to its National Environmental Laboratory Accreditation Program (NELAP), with assistance from other Agency staff involved in laboratory oversight and quality assurance activities. NELAP also provides staff support (including a Designated Federal Official) for the Environmental Laboratory Advisory Board (ELAB). ELAB is a Federal Advisory Committee chartered under the Federal Advisory Committee Act (FACA). Its purpose is to provide consensus advice to NELAC on behalf of NELAC Contributors.

Under the NELAC standards, the States and Federal agencies have primary authority for implementing the NELAC standards and operating environmental laboratory accreditation programs. The States have primary responsibility for

- ensuring conformance with the NELAC standards,
- conducting on-site assessments of laboratories, and
- granting, denying, or revoking accreditation status.

States may enter into agreements with third party organizations for conducting on-site assessments or providing other services to support their accreditation programs. When third parties are used as assessor bodies, the State retains authority for granting, denying or revoking accreditation status and for ensuring that the performance of

its third party(ies) meets NELAC standards. All on-site assessment personnel, whether employed by a State or by a third party working under agreement with a State, must successfully complete the NELAC on-site assessor training and must conduct all on-site assessments in accordance with the NELAC standards and with the procedures described in this manual.

1.4 Organization of This Manual

The remainder of this manual consists of five additional chapters:

- **Chapter 2, Assessment Principles and Practices**, provides general information on the role of on-site assessments in the laboratory evaluation process and on general principles and techniques for conducting audits.
- **Chapter 3, Assessor Conduct**, provides information concerning professional ethics for assessors, and timeliness and integrity in record keeping and reporting.
- **Chapter 4, The NELAC On-Site Assessment Process**, describes the on-site assessment process as established by Chapter 3 of the NELAC standards. It discusses training and qualifications required for on-site assessors, frequencies and reasons for conducting on-site assessments, pre-assessment, assessment, and follow-up activities.
- **Chapter 5, Assessment Criteria**, describes the criteria to be used by assessors to determine compliance with Chapter 5 (Quality Systems) of the NELAC standards. The text of this Chapter follows the outline of Chapter 5 of the standards and its Appendices. Evaluation procedures are clearly defined and linked to the specific requirements of the NELAC standards.

This manual is organized to reflect the NELAC standards and frequent references to specific sections of the standards are made throughout the document. Assessors should always take steps to ensure that they are referring to the most recent version of this manual, especially when using it for reference purposes, and should determine whether the most recent version takes into account the results of the most recent annual Conference. The current version of the NELAC standards is available on-line through the NELAC Home Page at: <http://ttnwww.rtpnc.epa.gov>.